

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraphs beginning on page 15, line 15, through page 16, line 10, with the following:

The retainer portion 715 of the frame 615 has a diameter that is larger than the diameter of the valve protector portion 720. When the bronchial isolation device 610 is deployed within a bronchial passageway, the diameter of the retainer portion 715 is sufficiently large to cause the retainer portion 715 to press against and anchor to the walls of the bronchial passageway to secure the bronchial isolation device 610 in a fixed location relative to the bronchial passageway. Each retainer cell [[712]] 712a of the frame 615 may be shaped to have a curved, distal edge 725 and a curved, proximal edge 730 that both assist in anchoring the retainer portion 715 to the bronchial passageway, as described more fully below. Each cell [[712]] 712a is attached to an adjacent cell [[712]] 712b at a cell junction 735.

With reference still to Figure 7, the valve protector portion 720 has valve protector cells 712b, which are smaller than the retainer cells 712a of the retainer portion 715 in order to compensate for the smaller diameter of the valve protector portion 720. Each valve protector cell 712b may have a curved, distal edge 735 and a curved, proximal edge 740. As mentioned, the size and shape of the valve protector cells [[712]] 712b and the retainer cells 712a can vary. The valve protector portion 720 at least partially surrounds the valve member 620 to maintain a default shape of the valve member, as described more fully below. The valve protector portion 720 can be rigid or flexible and it can be configured to collapse and expand.

Please replace the paragraph on page 18, lines 18-24, with the following:

Another mechanism that can be employed to achieve the two-state frame size is spring resilience. The insertion state can be achieved through a preconstraint of the frame 615 within the elastic range of the frame material. Once positioned in the bronchial passageway, the frame 615 can be released from constraint so that ~~[[it]]~~ spring resilience causes it to expand into an anchoring state. Constraining tubes or other mechanisms may achieve the initial insertion state.

Please replace the paragraph on page 19, lines 13-21, with the following:

The frame 615 can be manufactured of a variety of bio-compatible materials. In one embodiment, the frame 615 is manufactured of a superelastic material, such as Nitinol, that is heat-treated to attain the shape shown in Figure 7. In one embodiment, the entire frame 615 is manufactured out of a single piece of tubing made out of Nitinol or some other material. Figure 9 shows an isometric view of a tubular piece of material ~~[[1010]]~~ that has been cut into a pattern that forms the desired strut pattern. Once the material ~~[[1010]]~~ has been cut, such as through laser-cutting or chemical etching, the material ~~[[1010]]~~ is expanded and optionally heat treated so that it attains the shape shown in Figure 10.

Please replace the paragraphs beginning on page 20, line 23, through page 21, line 13, with the following:

Figure 12 shows another embodiment of the frame 615 (including the membrane 625) that includes two retainer portions including a proximal retainer portion 715a and a distal retainer portion 715b. A central valve protector portion 720 is disposed in-between the proximal retainer portion 715a and the distal retainer

portion 715b and connected thereto by linking struts 745. The retainer portions 715a,b have larger diameters than the valve protector portion 720 so that the ~~[[retainer]]~~ frame 615 has an hourglass-like shape. It should be appreciated that the diameter of the proximal retainer portion ~~[[615a]]~~ 715a is not necessarily equal to the diameter of the distal retainer portion ~~[[615b]]~~ 715b.

The dual retainer portions 715a, 715b can provide an increase in stability when the bronchial isolation device 610 is mounted in a bronchial passageway, as both retainer portions 715a, 715b provide independent anchors to the bronchial wall. Both retainer portions 715a, 715b also provide seals against the bronchial wall in which the bronchial isolation device is mounted. Thus, if the anchor or seal in one of the retainer portions weakens or fails, the other anchor portion 715a~~[[, 715]]~~ or 715b can compensate for the weakened or failed seal.

Please replace the paragraph beginning on page 33, line 12, through page 34, line 2, with the following:

In one embodiment, the valve member 620 comprises a duckbill valve that permits flow in one direction and prevents or restricts flow in a second direction. Figures 23-25 show an embodiment of a valve member 620 comprised of a duckbill valve 2310 that can be used in the bronchial isolation device 610. The duckbill valve 2310 includes a tubular base 2315 that has an outer diameter that fits within the annular valve protector portion 720 of the frame 615. As best shown in Figures 23 and 25, the duckbill valve 2310 includes a pair of opposed, inclined walls 2320 having ends that meet at lips 2325. The lips 2325 meet at two opposed corners. The walls 2320 can move with respect to one another so as to separate at the lips

2325 and form an opening through which fluid can travel. When exposed to fluid flow in a first direction (represented by the arrow 2330 in Figure 23) at the cracking pressure, the walls 2320 separate from one another to form the opening. When exposed to fluid flow in a second direction (represented by the arrow 2335 in Figure 23), the walls 2320 remain closed and prevent fluid from flowing through the duckbill valve ~~[[2320]]~~ 2310.

Please replace the paragraph beginning on page 35, line 20, through page 36, line 8, with the following:

There may be situations where a controlled reverse flow through a one-way valve might be desirable. Figures 28A and 28B shows an embodiment of a one-way duckbill valve 2702 that provides a controlled flow in a reverse direction. The valve 2702 behaves as a one-way valve in the forward direction (represented by the arrow 2704 in Figure 28A) in that the valve 2702 allows free flow of fluid through the valve at or above the valve's cracking pressure. The valve ~~[[2704]]~~ 2702 also allows a small, controlled rate of flow in the reverse direction (represented by the arrow 2706 in Figure 28A). In this regard, the duckbill valve ~~[[2704]]~~ 2702 includes a small flow channel 2708 that extends through the lips of the valve, as best shown in the enlarged view of Figure 28B. The flow channel 2708 allows fluid to flow in the reverse direction through the lips. The rate of flow is a function of the diameter and length of the flow channel ~~[[2530]]~~ 2708.

Please replace the paragraphs beginning on page 37, line 16, through page 38, line 21, with the following:

The membrane 625 defines a fluid pathway that is open at a distal end of the

frame 615 and that leads into the entry mouth 2903 of the valve 620. The general outer contour of the fluid pathway is represented by a bold line 2907 in Figure 29. In the valve protector ~~retainer~~ portion 715, the membrane 625 follows the outer contour of the frame 615 such that the fluid pathway is generally cylindrical in this portion of the frame 615. However, it is not necessary that the fluid pathway be cylindrical as long as it leads into the entry mouth 2903 of the valve member 620. Moreover, it is not necessary that the membrane cover the entire bronchial isolation device 610 as long as the membrane forms the fluid pathway. Moving toward the valve member 625, the outer contour of the membrane 625 slopes radially inward (as exhibited by the bold lines 2911) moving toward the entry mouth 2903 of the valve member 620. In this manner, the membrane 625 forms a funnel-shaped fluid pathway that leads into the valve member 620. The membrane 625 also forms radially-extending fins 2914 between the outer membrane wall of the funnel-shaped fluid pathway and the linking struts 745.

Figure 30 shows a cross-sectional view of bronchial passageway 2910 having interior walls 2915 that define a lumen of the bronchial passageway 2910. As is known to those skilled in the art, fluids can travel to and from a region of the lung through the lumen of the bronchial passageway 2910. The embodiment of the bronchial isolation device 610 of Figure 29 is shown positioned within the bronchial passageway ~~[[2915]]~~ 2910. The bronchial isolation device 610 is shown in Figure 30 with the membrane 625 trimmed along the distal edge of the frame 615. When the bronchial isolation device 610 is positioned within the bronchial passageway 2910, the frame 615 is in an expanded state so that it exerts a radial force against the

interior walls 2915, as represented by the arrows 2912 in ~~Figure 29~~ Figure 30. The radial force causes the frame 615 to press against the bronchial wall 2915 with a pressure sufficient to retain the bronchial isolation device 610 in a fixed position relative to the bronchial passageway. The distal edges 725 of the retainer cells 712a are positioned such that they lodge against the interior walls 2915 and inhibit the bronchial isolation device 610 from migrating in the distal direction 206.

Please replace the paragraphs beginning on page 38, line 22, through page 39, line 8, with the following:

As discussed above, the proximal edges 730 of the retainer cells 712a are attached to the linking struts 745. The linking struts 745 provide a smooth transition between the retainer section and the valve protector section of the frame 615. The linking struts 745 also lessen any sharpness of the proximal edges 730 of the retainer cells 712a and prevent the proximal edges 730 from penetrating into the bronchial wall 2915 if the bronchial isolation device 610 is pulled in the proximal direction ~~[[204]]~~ during removal. In addition, the linking struts 745 assist in radially constricting the retainer section of the frame 615 during removal of the bronchial isolation device 610. When the valve protector section is radially constricted (such as by using forceps that are deployed to the location of the bronchial isolation device 610), the linking struts 745 transfer the radial constriction to the retainer section of the frame 615.

Please replace the paragraph on page 40, lines 10-13, with the following:

In another embodiment, shown in Figure 32C, the frame strut 710 seals with the bronchial wall 2915 but the membrane ~~[[710]]~~ 625 does not necessarily seal with

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or contact the bronchial wall 2915. The situation shown in Figure 32C corresponds to use of the frame/membrane configuration shown in Figures 17D.